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09/881,686	06/18/2001	Sandrine Segura	016800-445	9187

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EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/881,686

Applicant(s)

SEGURA ET AL.

Examiner

Lauren Q Wells

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 5-7,30 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-29,31-43 and 47-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-49 are pending. Claims 5-7, 30 and 44-46 are withdrawn from consideration, as they are directed toward non-elected subject matter.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
The oath or declaration is not dated.

#### ***Election/Restrictions***

Claims 5-7, 30 and 44-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6, mailed January 15, 2002.

Applicant's election with traverse of the Election of Species Requirement in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Applicants believe it would not be an undue burden upon the Examiner to expand her search. This is not found persuasive. Applicant's instant composition comprises 9 or more constituents. Each of these constituents can comprise a large number of compounds/polymers and mixtures of compounds/polymers. The Examiner respectfully directs Applicant to the Election of Species requirement, wherein the Examiner listed all the possible compound/polymers encompassed by the 9 or more constituents. The possible combination of constituents and constituent mixtures is innumerable. Hence, such

a search would place an undue burden on the Examiner. Thus, the Election of Species requirement is still deemed proper and is therefore made FINAL.

A telephone conversation on March 6, 2002 with Erin Dunston and Norman Stepno clarified the Response to Requirement for Restriction filed February 13, 2002. As the aqueous phase, purified water was elected as the species. As the biologically active agent, nadifloxacin was elected as the species. As the co-surfactant, cetearth-20 was elected as the species.

Applicant's elected species was searched. The search was not extended because prior art was found to render the species obvious.

#### ***Claim Rejections - 35 USC § 112***

Claims 41-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cutaneous atrophy, stretch marks, alopecia, and acne, does not reasonably provide enablement for preventing cutaneous atrophy, stretch marks, alopecia and acne. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a method of treating or preventing cutaneous disorders as set forth in independent claims 41. A skilled practitioner in the art using the teachings of US Patent Nos. 6,136,332; 6,294,186; 6,068,847; 6,342,255; 6,319,957; 5,141,942; and 4,618,625 would be motivated to reduce or eliminate cutaneous atrophy, stretch marks, alopecia and acne. However, preventing cutaneous atrophy, stretch marks, alopecia and acne is inconsistent with what is known in the art since (1) reduction of cutaneous atrophy, stretch marks, alopecia and acne indicates that cutaneous atrophy, stretch marks, alopecia and acne is decreased, but not prevented; and (2) elimination of cutaneous atrophy, stretch marks, alopecia and acne indicates that symptoms of cutaneous atrophy, stretch marks, alopecia and acne may occur. Furthermore, prevention of cutaneous atrophy, stretch marks, alopecia and acne indicates that the subject never experiences any characteristics associated with cutaneous atrophy, stretch marks, alopecia and acne. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of cutaneous atrophy, stretch marks, alopecia and acne do not occur, and the state of the prior art indicating that the treatment is possible, all indicate that treatment, not prevention of cutaneous atrophy, stretch marks, alopecia and acne is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of oil-in-water emulsions comprising various active agents to determine which emulsions prevents cutaneous atrophy, stretch marks, alopecia and acne. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 41.

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**Note:** The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of cutaneous atrophy, stretch marks, alopecia and acne.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 18, 19, 27 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state" in claims 1 (lines 4-5) is vague and indefinite, as it is not clear what the active agent is solubilized in. Is it the emulsion as a whole? Is it the oil phase? Is it the aqueous phase? Furthermore, what is in micronized particulate state? Is it the active agent or is it the emulsion as a whole?

(ii) The phrase "at least 80%, numerically, of said micronized particles having diameters from 1 to 10 microns and at least 50%, also numerically, having diameters of less than 5 microns" in claim 1 (last 3 lines) is vague and indefinite, as it is confusing. Eighty percent plus fifty percent is over one hundred percent. Therefore, how can the composition comprise 80% of particles of 1-10 microns and 50% of less than 5 microns. If a range within a range is being claimed, this claim is rejected based on that.

(iii) The terms "major" and "minor" in claim 3 (lines 3 and 4) are relative terms which render the claim indefinite. The terms "major" and "minor" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(iv) The term "difficultly soluble" in claim 18 (line 3) is a relative term which renders the claim indefinite. The term "difficultly soluble" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(v) The term "pH conditions which are compatible with the skin" in claim 18 (lines 3-4) is a relative term which renders the claim indefinite. The term "pH conditions which are compatible with the skin" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(vi) The term "modulates" in claim 19 (line 3) is a relative term which renders the claim indefinite. The term "modulates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(vii) The phrase "a fatty acid or fatty alcohol, or derivative thereof" in claim 27 (lines 2-3) and the phrase "a cellulose derivative" in claim 38 (line 3) is vague and indefinite, as the metes and bounds of these claims are unascertainable. What compounds are encompassed by the phrase "derivative thereof"? The specification does not define these phrases and one of ordinary skill in the art would not be apprised of it.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-10, 18-24, 26-29, 40-43, 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. (EP 0268164) in view of Grollier et al. (6,136,332).

Lochhead et al. teach oil-in-water emulsions which contain a modified polymer which is a copolymer of an acrylic acid and a smaller amount of a long chain acrylate monomer, wherein the modified polymers function as primary emulsifiers or surfactants. The composition is disclosed as having a pH of about less than 6 is disclosed. A mixture of silicone oil and mineral oil is disclosed as comprising the oil phase. It is further disclosed that convention oil-in-water emulsions have a particle size of less than 10 microns and preferably 0.1-5 microns. The reference fails to teach an active agent. See pg. 2, line 28-pg. 14, line 10.

Grollier et al. teach dermatological/pharmaceutical compositions comprising volatile oils/phenylated silicone oils comprising at least one bioaffecting active agent, such as antiviral, antibacterial, antifungal, anti-inflammatory, neuromediator modulator, etc. Nadifloxacin is disclosed as an antibacterial active agent for use in the composition. See Col. 2, line 35-Col. 9, line 64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the nadifloxacin of Grollier et al. to the emulsion of Lochhead et al. because a) Grollier et al. and Lochhead et al. are both directed toward cosmetic compositions that impart skin care benefits; b) Grollier et al. teach their active agents as in composition with at least one volatile oil and Lochhead et al. teach oil-in-water emulsions comprising volatile silicone oils as constituents; c) Grollier et al. teach nadifloxacin as treating microbial infections such as acne or peribuccal impetigo and Lochhead et al teach compositions that have good cleansing effects and



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that open pores without being absorbed, wherein cleansing of the skin and opening pores is known to treat acne; hence, adding nadifloxacin to the compositions of Lochhead et al. would be within the skill of one in the art.

Claims 1-4, 8-29, 31-43, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (5,073,372) in view of Lochhead et al. in further view of Grollier et al., Pisson et al. (5,882,633), Kaplan (5,916,543), Klein (4,486,405) and Kim et al. (5,980,939).

Turner et al. teach leave-on facial emulsion compositions. Disclosed are oil-in-water emulsions comprising carboxylic acid copolymer, such as acrylates/C10-30 alkyl acrylate cross polymers, volatile silicone oils, and carboxyvinyl polymers (gelling agents). Waxes are further disclosed as oil phase constituents, as are pharmaceutical actives. The reference fails to teach particle size, preferred active ingredients, preferred surfactants, preferred co-surfactants, preferred wetting agents, and pH. See Col. 3, line 20-Col. 4, line 2; Col. 5, line 10-Col. 14, line 67.

Lochhead et al. is applied as discussed above.

Grollier et al. is disclosed as discussed above.

Pisson et al. teach cosmetic and/or dermatological compositions. Disclosed is an oil-in-water emulsion comprising Arlacel 165 (glyceryl and PEG-100), Pemulen TR1 (acrylic acid/C10-C30 alkyl acrylate), and water. Oils such as cyclomethicone and co-emulsifiers are disclosed for use in the composition. See Col. 10, line 3-Col. 13, line 15.

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Kaplan teaches oil-in-water emulsions having decreased skin rub-in times comprising a nonaqueous phase, an aqueous phase and an oil-in-water emulsifier. Ceteareth-20 is disclosed as a known oil-in-water emulsifier that enhances emulsion stability. See Col. 2, line 15-Col. 3, line 3.

Klein teaches a cosmetic composition comprising poloxamer 124 in composition with carbomer 940 (carboxyvinyl polymer) and water. See Col. 2, line 15-Col. 3, line 52; Col. 6, line 60-Col. 10, line 21.

Kim et al. teach cyclosporin containing pharmaceutical composition comprising an oil component and hydrophilic cosurfactant. Polyoxyethylene-polyoxypropylene block copolymer is disclosed as a preferred hydrophilic cosurfactant and poloxamer 124 is disclosed as the block copolymer. Poloxamer 124 is disclosed as a solubilizer for medicinal components and lipid emulsions and as thermally stable and well disclosed in organic solvents. See Col. 6, line 27-Col. 7, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Turner et al. and obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Turner et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Turner et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Turner et al. teach that pharmaceutical actives, such as antibiotics that induce a desired local or systemic effect can be incorporated into his emulsions, and Grollier et al. nadifloxacin as an antibacterials that imparts a local and system effect to skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Arlacel 165 of Pisson et al. into the emulsion of the combined references because a) Pisson et al. and the combined references both teach oil-in-water emulsions that impart benefits to the skin; b) Pisson et al. and the combined references teach oil-in-water emulsions comprising carboxyvinyl polymer, acrylates/C10-30 alkylacrylate cross polymer, and volatile silicone oils; c) Pisson et al. additionally teach Arlacel 165 in their emulsion; hence, the addition of Arlacel 165 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the cetareth-20 of Kaplan to the emulsion of the combined references because a) the combined references and Kaplan all teach oil-in-water cosmetic emulsions that impart skin care benefits; b) the combined references teach emulsions comprising co-surfactants such as glyceryl monohydroxy stearate and Kaplan et al. teach cetareth-20 and glycerol monostearate as interchangeable and combinable co-surfactants; c) Kaplan et al. also teach that mixtures of

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emulsifiers (surfactants) are frequently desirable for enhancing emulsion stability; hence, the addition of cetareth-20 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Klein exemplifies compositions comprising poloxamer 124, water and carbomer (carboxyvinyl polymer) and Turner et al. teach their composition as comprising water and carbomer; c) Kim et al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, the addition of poloxamer 124 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

Claims 1-4, 8-29, 31-43, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evan et al. (5,750,122) in view of Lochhead et al. in further view of Grollier et al., Pisson et al., Klein, and Kim et al.

Evans et al. teach compositions for treating hair or skin. Disclosed is an anti-acne oil-in-water emulsion comprising water, glycerin, carbomer (carboxyvinyl polymer), acrylates/c10-30 alkylacrylates crosspolymer, stearyl alcohol, cetyl alcohol and PEG-4. Volatile silicone agents are disclosed as conditioning agents for use in the composition. The reference fails to teach particle size, preferred active ingredients, preferred surfactant, preferred co-surfactant, and preferred wetting agent. See Col. 2, line 17-Col. 17, line 20.

Lochhead et al. is applied as discussed above.

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Grollier et al. is disclosed as discussed above.

Pisson et al. is applied as discussed above.

Klein is applied as discussed above.

Kim et al. is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Evans et al. and obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Evans et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Evans et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Evans et al. teach that antimicrobial agents and anti-acne agents can be added to their emulsion, and Grollier et al. nadifloxacin as an antibacterial, anti-acne agent for use in skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Arlacel 165 of Pisson et al. into the emulsion of the combined references because a) Pisson et al. and the combined references both teach oil-in-water emulsions

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that impart benefits to the skin; b) Pisson et al. and the combined references teach oil-in-water emulsions comprising carboxyvinyl polymer, acrylates/C10-30 alkylacrylate cross polymer, and volatile silicone oils; c) Pisson et al. additionally teach Arlacel 165 in their emulsion; hence, the addition of Arlacel 165 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Klein exemplifies compositions comprising poloxamer 124, water and carbomer (carboxyvinyl polymer) and Evans et al. teach their composition as comprising water and carbomer; c) Kim et al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, the addition of poloxamer 124 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

Claims 1-4, 8-29, 31-43, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisson et al. in view of Lochhead et al. in further view of Grollier et al., Kaplan, Klein, and Kim et al.

Pisson et al. is applied as discussed above. The reference fails to teach particle size, preferred active agents, preferred co-surfactants, preferred wetting agents, preferred gelling agents, and pH.

Lochhead et al. is applied as discussed above.

Grollier et al. is applied as discussed above.

Kaplan is applied as discussed above.

Klein is applied as discussed above.

Kim is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Pisson et al. and obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Pisson et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Evans et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Pisson et al. teach typical additives and adjuvants in the cosmetics field that impart benefit to the skin can be added to their emulsion, and Grollier et al. nadifloxacin as an antibacterial, anti-acne agent for use in skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the cetareth-20 of Kaplan to the emulsion of the combined references because a) the combined references and Kaplan all teach oil-in-water cosmetic emulsions that impart skin

care benefits; b) the combined references teach emulsions comprising surfactants, such as glyceryl monostearate and polyethylene glycol stearate mixture, and co-surfactants, and Kaplan teaches cetareth-20, glyceryl monostearate, and polyethylene glycol stearate as interchangeable and combinable surfactants; c) Kaplan also teaches that mixtures of emulsifiers (surfactants) are frequently desirable for enhancing emulsion stability; hence, the addition of cetareth-20 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Kim et al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, the addition of poloxamer 124 to the composition of the combined references for cosmetic purposes would be within the skill of one in the art.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### ***Unexpected Results***

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing"



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*In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 15-22 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition as a skin cosmetic. This is seen to be an expected result based on the cited prior art.

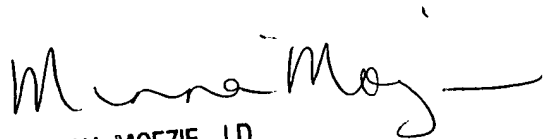
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
March 7, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600